12 HOUR ALLERGY AND CONGESTION- loratadine, pseudoephedrine sulfate tablet, film coated, extended release Walgreen Company

Walgreen Co. Wal-itin D 12 Hour Allergy & Congestion Drug Facts

Active ingredients (in each tablet)

Loratadine 5 mg

Pseudoephedrine sulfate 120 mg

Purpose

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- sneezing
- itchy, watery eyes
- runny nose
- itching of the nose or throat
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- thyroid disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland

• liver or kidney disease. Your doctor should determine if you need a different dose.

When using this product do not take more than directed.

Taking more than directed may cause drowsiness.

Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve within 7 days or are accompanied by a fever
- nervousness, dizziness or sleeplessness occurs

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

• do not divide, crush, chew or dissolve the tablet

adults and children 12 years and over	1 tablet every 12 hours; not more than 2 tablets in
	24 hours
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- each tablet contains: calcium 25 mg
- do not use if blister unit is broken or torn
- store between 20° to 25°C (68° to 77°F)
- keep in a dry place

Inactive ingredients

croscarmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, pharmaceutical ink, povidone, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

NON-DROWSY*

Wal-itin® D

Compare to Claritin-D[®] 12 Hour Tablets active ingredients

12 HOUR ALLERGY & CONGESTION

PSEUDOEPHEDRINE SULFATE 120 mg / NASAL DECONGESTANT

LORATADINE 5 mg / ANTIHISTAMINE

EXTENDED-RELEASE TABLETS

12 HOUR - EXTENDED RELEASE TABLETS

INDOOR & OUTDOOR ALLERGIES

12-hour relief of: nasal & sinus congestion due to colds or allergies; sneezing; runny nose; itchy, watery eyes & itchy throat or nose due to allergies

30 EXTENDED-RELEASE TABLETS

*WHEN TAKEN AS DIRECTED. SEE DRUG FACTS PANEL.

12 HOUR

ACTUAL SIZE

Walgreens

HOUR ALLERGY & CONGESTION

PSEUDOEPHEDRINE SULFATE 120 mg / NASAL DECONGESTANT LORATADINE 5 mg / ANTIHISTAMINE Extended-release Tablets

*WHEN TAKEN AS DIRECTED. SEE DRUG FACTS PANEL.

ORG0918-F REV-0519

NON-DROWSY*

Walgreens

Compare to Claritin-D® 12 Hour Tablets active ingredients#

12 HOUR ALLERGY & CONGESTION

NDC 0363-1133-65

PSEUDOEPHEDRINE SULFATE 120 mg / NASAL DECONGESTANT LORATADINE 5 mg / ANTIHISTAMINE EXTENDED-RELEASE TABLETS

12 HOUR EXTENDED-RELEASE TABLETS

INDOOR & OUTDOOR ALLERGIES

12-hour relief of: nasal & sinus congestion due to colds or allergies; sneezing; runny nose; itchy, watery eyes & itchy throat or nose due to allergies

EXTENDED-RELEASE

*WHEN TAKEN AS DIRECTED. SEE DRUG FACTS PANEL.





Drug Facts

Active ingredients (in each tablet) Purpose

Ikes

- ■temporarily relieves these symptoms due to hay feveror other upper respiratory allergies:
- ■s neezing ■itchy, watery eyes ■runny nose ■itching of the nose or throat
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of n as al pas sages
- temporarily relieves sinus congestion and pressure temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibi br (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkins on's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmas is the fore taking this product.

Ask a doctor before use if you have

- heart disease thyroid disease high blood pressure
 diabetes trouble urinating due to an enlarged prostate gland
 liveror kidney disease. Your doctors hould determine if you
- need a different dose.

Drug Facts (continued)

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms donot improve within 7 days or are accompanied by a fever
- nervous ness, diz ziness or slæples sness occurs

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1 -800-222-1 222).

Directions ■ do not divid e, crush, chew or dissolve the tablet 1 tab letevery 1 2 hours; not more than 2 tablets in 2 4 hours adults and children 12 years and over

children under 12 years of age ask a doctor consumers with liver or ask a doctor kidney disease

Ot her in formation

- each tab let contains: calcium 25 mg ■ donot use if blister unit is broken or torn
- store between 20° to 25° C (68° to 77 °F)
- keep in a dry place

Inact ive ingredients croscamellose sodium, dibasic calcium phosphate, hypromellose, lactos e monohydrate, magnesium stearate, pharmaceutical ink, povidone, titanium dioxide

Drug Facts (continued)

Questions or comments?1-800-719-9260

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

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12 HOUR ALLERGY AND CONGESTION

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1133
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	5 mg	
PSEUDO EPHEDRINE SULFATE (UNII: Y9 DL7QPE6B) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDO EPHEDRINE SULFATE	120 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTO SE MONO HYDRATE (UNII: EWQ57Q8 I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics				
Color	WHITE (to off-white)	Score	no score	
Shape	ROUND	Size	12mm	
Flavor		Imprint Code	7U0	
Contains				

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-1133-46	10 in 1 CARTON	05/05/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-1133-60	20 in 1 CARTON	05/05/2018	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0363-1133-65	30 in 1 CARTON	05/05/2018	
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076050	05/05/2018	

Labeler - Walgreen Company (008965063)

Revised: 11/2020 Walgreen Company